



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2022-0833; FRL-10361-01-ORD]

Availability of the IRIS Assessment Plan and Protocol for Assessing Cancer Risk from Inhalation Exposure to Cobalt and Cobalt Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period associated with release of the Integrated Risk Information System (IRIS) Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer). This document communicates information on the scoping needs identified by EPA program and regional offices and the IRIS Program's initial problem formulation activities. Specifically, the assessment plan outlines the objectives for the IRIS assessment and the type of evidence considered most pertinent to address the scoping needs. The systematic review protocol describes the methodology of how the assessment will be conducted, including dose-response considerations. EPA is releasing this IRIS assessment plan and systematic review protocol for a 30-day public comment period in advance of a public science webinar planned for November 30, 2022. The Agency encourages the public to comment on all aspects of the assessment plan and the systematic review protocol, including key science issues and identification of any new or missing studies.

DATES: The 30-day public comment period begins **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and ends **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: The IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer) will be available via the Internet on the IRIS website at <https://www.epa.gov/iris/iris-recent-additions> and in the public docket at <http://www.regulations.gov>, Docket ID No. EPA-HQ-ORD-2022-0833.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202-566-1752; facsimile: 202-566-9744; or e-mail: Docket_ORD@epa.gov.

For technical information on the IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer), contact Garland Waleko, CPHEA; e-mail: Waleko.garland@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About IRIS Assessment Plans and Systematic Review Protocols

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative information on the health effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides high quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. As part of scoping and initial problem formulation activities prior to the development of an assessment, the IRIS Program carries out a broad, preliminary literature survey to assist in identifying health effects that have been studied in relation to the chemical or substance of interest, as well as science issues that may need to be considered when evaluating toxicity. This information, in conjunction with scoping needs identified by EPA program and regional offices, is used to inform the development of an IRIS assessment plan (IAP).

The IAP communicates the plan for developing each individual chemical assessment to the public and includes summary information on the IRIS Program's scoping and initial problem formulation activities, objectives and specific aims for the assessment, and a PECO (Populations, Exposures, Comparators, and Outcomes) for the systematic review. The PECO provides the

framework for developing detailed literature search strategies and inclusion/exclusion criteria, particularly with respect to evidence stream (e.g., human, animal, mechanistic), exposure measures, and outcome measures. EPA also presents a methods document, referred to as the systematic review protocol, for conducting a chemical-specific systematic review of the available scientific literature. Systematic review protocols describe screening criteria to identify relevant literature, outline the approach for evaluating study quality, and describe the dose-response methods.

II. Public Webinar Information

To allow for public input, EPA is convening a public webinar to discuss the IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer) on November 30, 2022. Specific teleconference and webinar information regarding this public meeting will be provided through the IRIS website (<https://www.epa.gov/iris>) and via EPA's IRIS listserv. To register for the IRIS listserv, visit the IRIS website (<https://www.epa.gov/iris>) or visit <https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-system#connect>.

III. How to Submit Technical Comments to the Docket at <https://www.regulations.gov>

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2022-0833 for IRIS Assessment Plan and Systematic Review Protocol for Inhalation Exposure to Cobalt and Compounds (Cancer), by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- E-mail: Docket_ORD@epa.gov.
- Fax: 202-566-9744.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The phone number is 202-566-1752.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2022-0833.

Please ensure that your comments are submitted within the specified comment period.

Comments received after the closing date will be marked “late,” and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through www.regulations.gov or e-mail that you consider to be CBI or otherwise protected. The www.regulations.gov website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit the EPA Docket Center homepage at www.epa.gov/epahome/dockets.htm.

Docket: Documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

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Assessment.

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